

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

V.

APOTEX, INC., and
APOTEX CORP.

Defendants.

Civil Action No. 3:10-cv-05810 (MLC)(LHG)

Electronically Filed

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 and the Pretrial Scheduling Order, Plaintiff Bristol-Myers Squibb Company (“BMS”), together with Defendants Apotex, Inc. and Apotex Corp. (“Apotex”) hereby provide their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 6,596,746 (“the ‘746 patent”), 7,125,875 (“the ‘875 patent”), 7,153,856 (“the ‘856 patent”) and 7,491,725 (“the ‘725 patent”).

I. LOCAL PATENT RULE 4.3(a) - CONSTRUCTION OF CLAIM TERMS UPON WHICH THE PARTIES AGREE

In accordance with Local Patent Rule 4.3(a), the parties agree that the following terms should be construed as follows:

See **Exhibit A**, attached hereto.

II. LOCAL PATENT RULE 4.3(b) - PROPOSED CONSTRUCTION OF DISPUTED CLAIM TERMS

In accordance with Local Patent Rule 4.3(b), each party's proposed construction for the disputed claim terms is as follows:

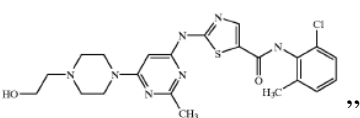
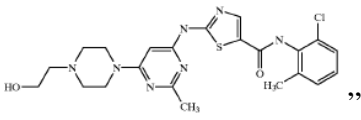
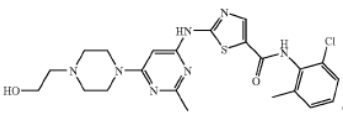
See **Exhibit B**, attached hereto.

As required by Local Patent Rule 4.3(b), the table attached as Exhibit B identifies the intrinsic and extrinsic evidence that each party intends to rely upon in support of its respective constructions or to oppose the opposing party's proposed constructions.

III. LOCAL PATENT RULE 4.3(c) - SIGNIFICANT OR DISPOSITIVE CLAIM TERMS

BMS Position: None

Apotex Position: Apotex believes the following claim terms are significant, even if not case dispositive because they may assist in streamlining issues in the case:

- '746 patent, claim 43: "The compound ,"
 - '856 patent, claim 1: "the compound ,"
 - '725 patent, claims 1, 3, 12: "Crystalline monohydrate of the compound of formula (IV)"
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- '725 patent, claim 2: "The compound of claim 1"
 - '725 patent, claims 4, 5, 8, 9: "The compound of claim 3"
 - '725 patent, claims 6, 7: "A process for preparing the compound of claim 3"
 - '725 patent, claims 10, 11, 14, 16: "The compound of claim 9"
 - '725 patent, claims 13, 15, : "The compound of claim 12"

IV. LOCAL PATENT RULE 4.3(d) - ANTICIPATED TIME NEEDED FOR CLAIM CONSTRUCTION HEARING

In accordance with Local Patent Rule 4.3(d), the parties agree and respectfully request that the claim construction hearing consist of both attorney argument and limited live testimony of expert witnesses as described below in Section V. The parties estimate that the claim construction hearing will require approximately 3 hours of attorney argument, and, should the court permit expert witness testimony, an additional approximately 2 hours of expert witness testimony with the time being equally allotted to each side.

V. LOCAL PATENT RULE 4.3(e) - IDENTIFICATION OF ANTICIPATED WITNESSES FOR CLAIM CONSTRUCTION HEARING

In accordance with Local Patent Rule 4.3(e), the parties propose calling the following expert witnesses for live testimony at the claim construction hearing:

- BMS Expert Witnesses: Dr. Atwood (summary of testimony attached as Exhibit C) and Dr. Jorgensen (summary of testimony attached as Exhibit D).
- Apotex Expert Witnesses: Dr. Ariel Fernandez (summary of testimony attached as Exhibit E) and Dr. Gautam Desiraju (summary of testimony attached as Exhibit F).

Date: March 2, 2012

<p>BRISTOL-MYERS SQUIBB COMPANY</p> <p><u>/s/ Liza M. Walsh</u></p> <p>Liza M. Walsh Christine I. Gannon CONNELL FOLEY, LLP 85 Livingston Avenue Roseland, New Jersey 07068 Tel. (973) 535-0500 Fax. (973) 535-9217</p>	<p>APOTEX, INC. AND APOTEX CORP.</p> <p><u>s/ Arnie Calmann</u></p> <p>Arnold B. Calmann Geri L. Albin SAIBER LLC One Gateway Center 10th Floor, Suite 1000 Newark, New Jersey 07102 (973) 622-3333</p>
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<p>Leora Ben-Ami Benjamin C. Hsing Jeanna Wacker KAYE SCHOLER LLP 425 Park Avenue New York, New York 10022 Tel. (212) 836-8000 Fax. (212) 836-8689</p> <p><i>Attorneys for Plaintiff Bristol-Myers Squibb Company</i></p>	<p>William A. Rakoczy Paul J. Molino Tara M. Raghavan Luke T. Shannon RAKOCZY MOLINO MAZZOCHI SIWIK LLP 6 West Hubbard Street, Suite 500 Chicago, Illinois 60654 (312) 222-6301</p> <p><i>Attorneys for Defendants Apotex Inc. and Apotex Corp.</i></p>
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EXHIBIT A

EXHIBIT A

CLAIM	CLAIM TERM	AGREED UPON CONSTRUCTION
'746 claim 7; '746 claim 44; '746 claim 47;	"an amount effective"	An amount of a compound capable of treating a protein kinase-associated disorder as determined by one of ordinary skill in the art understanding that the specific dose level and frequency of dosage for any particular subject may be varied and will depend upon a variety of factors.
'746 claim 7	"A method for the treatment of a protein tyrosine kinase-associated disorder"	A method for the prevention, alleviation or therapy of a protein tyrosine kinase-associated disorder. "Protein-tyrosine kinase-associated disorders" are those disorders which result from aberrant tyrosine kinase activity, and/or which are alleviated by the inhibition of one or more of these enzymes.
'746 claim 18	"wherein said protein tyrosine kinase-associated disorder is cancer."	Where the "protein-tyrosine kinase-associated disorder" -- <i>i.e.</i> , a disorder which results from aberrant tyrosine kinase activity, and/or which is alleviated by the inhibition of one or more of these enzymes -- is cancer.
'746 claim 42	"A pharmaceutical composition for the treatment of a protein tyrosine kinase-associated disorder"	A pharmaceutical or medicinal preparation comprising at least the recited ingredients for the prevention, alleviation, or therapy of a protein tyrosine kinase-associated disorder. "Protein-tyrosine kinase-associated disorders" are those disorders which result from aberrant tyrosine kinase activity, and/or which are alleviated by the inhibition of one or more of these enzymes.
'746 claim 44	"A method for the treatment of cancer"	A method for the prevention, alleviation or therapy of cancer
'746 claim 47	"A method for the treatment of a protein tyrosine kinase-associated disorder"	A method for the prevention, alleviation, or therapy of a protein tyrosine kinase-associated disorder. "Protein-tyrosine kinase-associated disorders" are those disorders which result from aberrant tyrosine kinase activity, and/or which are alleviated by the inhibition of one or more of these enzymes
'856 claim 1	"A method for the treatment of cancer"	A method for the prevention, alleviation, or therapy of cancer
'856 claim 1	"an amount effective"	An amount of a compound capable of treating a cancer as determined by one of ordinary skill in the art understanding that the specific dose level and frequency of dosage for any particular subject may be varied and will depend upon a variety of factors

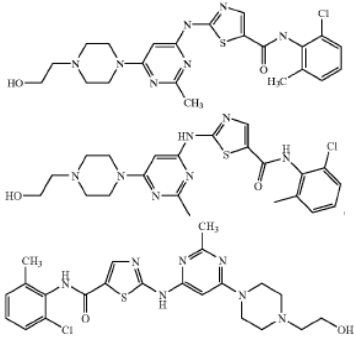
EXHIBIT A

'875 claim 1; '875 claim 2; '875 claim 3;	"A method for the treatment of a cancer"	A method for the prevention, alleviation, or therapy of cancer.
'875 claim 1; '875 claim 2; '875 claim 3;	"an effective amount"	An amount of a compound of formula III capable of treating a cancer as determined by one of ordinary skill in the art understanding that the specific dose level and frequency of dosage for any particular subject may be varied and will depend upon a variety of factors.
'875 claim 3	"an effective amount of a therapeutic agent"	An amount of a therapeutic agent, other than a compound of formula III, capable of treating a cancer, as determined by one of ordinary skill in the art understanding that the specific dose level and frequency of dosage for any particular subject may be varied and will depend upon a variety of factors
'875 claim 11; '875 claim 27	"A method for the oral treatment of cancer"	A method for the prevention, alleviation, or therapy of cancer via oral means.
'875 claim 11; '875 claim 27	"an effective amount"	An amount capable of treating a cancer as determined by one of ordinary skill in the art understanding that the specific dose level and frequency of dosage for any particular subject may be varied and will depend upon a variety of factors
'725 claim 4; '725 claim 13; '725 claim 14	"a therapeutically effective amount of"	An amount that when administered is effective to prevent, suppress or ameliorate the disease or condition or the progression of the disease or condition.

EXHIBIT B

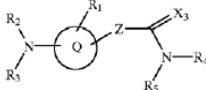
EXHIBIT B

CLAIM	CLAIM TERM	BRISTOL-MYERS	APOTEX
'746 claim 6	"A compound or salt thereof selected from the group consisting of"	<p>CONSTRUCTION</p> <p>Plain meaning as understood by a person of ordinary skill in the art. "Salt" denotes acidic and/or basic salts formed with inorganic and/or organic acid and bases. In addition, "selected from the group consisting of" is a well accepted form of alternative expression commonly referred to as a Markush group. Thus, any pharmaceutical composition containing a compound listed in this claim would fall within the scope of the claim.</p> <p>EVIDENCE</p> <p><i>See, e.g., '746 patent at col. 6, ll. 18-35; col. 25, ll. 23-35</i></p>	<p>CONSTRUCTION</p> <p>One compound or salt thereof selected from the following group of compounds; where the term "salt" denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts, and including both pharmaceutically- acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof. By virtue of its use of the language "selected from the group consisting of," this term excludes those compositions containing one or more compounds not claimed in claim 6, including, but not limited to, for example, impurities.</p> <p>EVIDENCE</p> <p>Col. 6, l. 21-col. 7, l. 17; <i>id.</i> at col. 276, l. 52 – col. 297, l. 37.</p> <p>'746 patent Prosecution History ("PH"), Original Application; 8/23/02 Response After Final Rejection at 10-35.</p> <p>Manual of Patent Examining Procedure ("MPEP") § 803.02.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

	<p>Chemical names identified in claim 6 including but not limited to “N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide.”</p>	<p>CONSTRUCTION</p> <p>‘N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide represents the compound having the following equivalent chemical structures:</p>  <p>EVIDENCE</p> <p>Dr. Jorgensen <i>See also</i> claim 43, <i>infra</i></p>	<p>CONSTRUCTION</p> <p>The chemical descriptors given in claim 6 require the plain and ordinary meaning of such terms, to be interpreted according to IUPAC nomenclature guidelines.</p> <p>EVIDENCE</p> <p>‘746 patent at col. 6, l. 21-col. 7, l. 17; <i>id.</i> at col. 276, l. 52 – col. 297, l. 37.</p> <p>‘746 patent Prosecution History (“PH”), Original Application; <i>id.</i>, 8/23/02 Response After Final Rejection at 10-35.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>A GUIDE TO IUPAC NOMENCLATURE OF ORGANIC COMPOUNDS RECOMMENDATIONS 1993 (R. Panico et al., eds., Blackwell Science 1994) (APO(Das)025796- 6000).</p>
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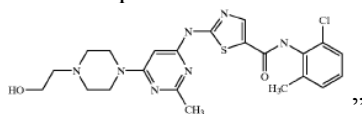
<p>‘746 claim 7</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col.25, ll. 36-54</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘746 patent at col. 23, ll. 32-37; col. 26, l. 39- col. 28, l. 44.</p> <p>‘746 patent PH, 8/23/02 Response After Final Action at 35-39, 45.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.,</i> col. 26, ll. 53-57</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder known to be susceptible to treatment with compounds of formula III, as construed above, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘746 patent at col. 1, ll. 9-14; <i>id.</i> at col. 22, l. 66-col. 25, l. 22.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>see also Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment” . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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	<p>“of at least one compound of formula III or a salt thereof”</p> <p style="text-align: right;">III</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art. “Salt” denotes acidic and/or basic salts formed with inorganic and/or organic acid and bases.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 6, ll. 18-35</p>	<p>CONSTRUCTION At least one compound falling within the scope of compounds that may result from formula III as further defined by the language of claim 7, or a salt thereof; where the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof. The claim term is exclusive of those compositions containing one or more compounds not described by Formula III, including, but not limited to, for example, impurities.</p> <p>EVIDENCE ‘746 patent at col. 6, l. 21-col. 7, l. 17.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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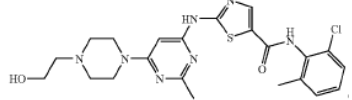
**‘746
claim 43**

“The compound



CONSTRUCTION

The compound represented by ‘N-(2-Chloro-6-methylphenyl)-2-[[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide, and is the same as



EVIDENCE

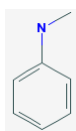
Dr. Jorgensen

See, e.g., Examples 1-580, including Example 455; ; file histories of the ‘746 patent, 856 patent and ‘875 patent.

See also the ‘875 and ‘725 patents; Principles of Chemical Nomenclature, ed. G.J. Leigh (1998), p.11 (“Another way of presenting structural formulae is by using bonds only, with the understanding that carbon and hydrogen atoms are never explicitly shown.”); and the following illustrative examples:

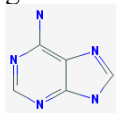
U.S. Patent No. 5,470,855 (col. 7, lines 15-22)

U.S. Patent No. 6,677,457 (col. 1, lines 40-49)



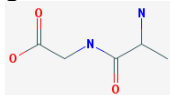
N-methylaniline

<http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=150592>



Adenine

http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=125011544&loc=es_rss



Alanine-Glycine

http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=125539425&loc=es_rss 6

CONSTRUCTION

A compound with the structure expressly identified in the claim, wherein this structure cannot represent a compound known as dasatinib.

EVIDENCE

The ‘746 patent PH, 6/11/01 Restriction Requirement; *id.*, 7/10/01 Response to Restriction Requirement; *id.*, 5/6/02 Response at 27, 29; *id.*, 8/23/02 Response After Final Rejection at 7, 46.

‘746 patent at claim 43.

‘875 patent at claims 2, 11, 15, 19, 20, 21, 22, 23, 24, 25 and 27.

‘725 patent at claims 1, 3, and 12.

file histories of the ‘746 patent, ‘856 patent and ‘875 patent.

A GUIDE TO IUPAC NOMENCLATURE OF ORGANIC COMPOUNDS RECOMMENDATIONS
1993 (R. Panico et al., eds., Blackwell Science 1994)
(APO(Das)025796- 6000).

Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.

<p>‘746 claim 44</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col.25, ll. 36-54</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘746 patent at col. 23, ll. 32-37; <i>id.</i> at col. 26, l. 39-col. 28, l. 44.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.</i>, col. 26, ll. 53-57</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder known to be susceptible to treatment with the compound of claim 43, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘746 patent at col. 1, ll. 9-14; <i>id.</i> at col. 22, l. 66-col. 25, l. 22.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07- 1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment” . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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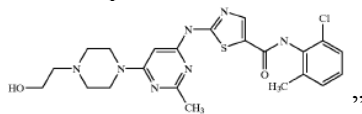
<p>‘746 claim 47</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col.25, ll. 36-54</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘746 patent at col. 23, ll. 32-37; <i>id.</i> at col. 26, l. 39-col. 28, l. 44.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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<p>‘856 claim 1</p>	<p>“administering orally to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially the compound in oral form, including but not limited to tablets, capsules, granules or powders.</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, ll. 39-41</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Administration may be accomplished via any oral route (including but not limited to, in the form of tablets, capsules, granules or powders) either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘856 patent at col. 26, ll. 32-41; <i>id.</i> at col. 28, ll. 39-41; <i>id.</i> at col. 29, ll. 41-59.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition”).</p>
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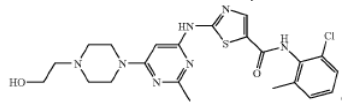
	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.,</i> col. 29, ll. 56-59</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder known to be susceptible to treatment with the compound of claim 1, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘856 patent at col. 1, ll. 15-20; <i>id.</i> at col. 25, l. 56-col. 28, l. 25.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term. <i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment’ . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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“the compound



CONSTRUCTION

The compound represented by ‘N-(2-Chloro-6-methylphenyl)-2-[[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide, and is the same as



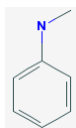
EVIDENCE

Dr. Jorgensen

See, e.g., Examples 1-580, including Example 455; file histories of the ‘746 patent, 856 patent and ‘875 patent. *See also* the ‘875 and ‘725 patents; Principles of Chemical Nomenclature, ed. G.J. Leigh (1998), p.11 (“Another way of presenting structural formulae is by using bonds only, with the understanding that carbon and hydrogen atoms are never explicitly shown.”); and the following illustrative examples:

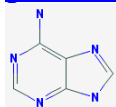
U.S. Patent No. 5,470,855 (col. 7, lines 15-22)

U.S. Patent No. 6,677,457 (col. 1, lines 40-49)



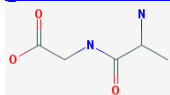
N-methylaniline

<http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=150592>



Adenine

http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=125011544&loc=es_rss



Alanine-Glycine

http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=125539425&loc=es_rss

CONSTRUCTION

A compound with the structure identified in the claim, wherein this structure cannot represent a compound known as dasatinib.

EVIDENCE

‘856 patent at claim 1.

The ‘746 patent PH, 6/11/01 Restriction Requirement; *id.*, 7/10/01 Response to Restriction Requirement; *id.*, 5/6/02 Response at 27, 29; *id.*, 8/23/02 Response After Final Rejection at 7, 46.

‘856 patent PH, 5/8/06 Amendment After Allowance at 2.

See also generally file histories of the ‘746 patent, ‘856 patent and ‘875 patent.

‘746 patent at claim 43.

‘875 patent at claims 2, 11, 15, 19, 20, 21, 22, 23, 24, 25 and 27.

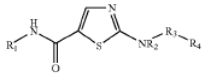
‘725 patent at claims 1, 3, and 12.

Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.

A GUIDE TO IUPAC NOMENCLATURE OF ORGANIC COMPOUNDS RECOMMENDATIONS 1993 (R. Panico et al., eds., Blackwell Science 1994) (APO(Das)025796-6000).

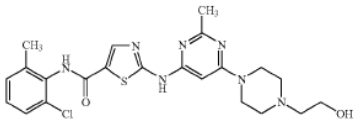
<p>‘875 claim 1</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, l. 52 - col. 29, l. 3</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘875 patent at col. 26, ll. 36-41; <i>id.</i> at col. 28, l. 52-col. 29, l. 3; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 22-col. 31, l. 11.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.,</i> col. 30, ll. 1-4</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder susceptible to treatment with the compound of formula III or a salt thereof, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘875 patent at col. 1, ll. 10-17; <i>id.</i> at col. 28, ll. 26-38.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase “‘in need of such treatment’ . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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	<p>“the compound of formula III or a salt thereof”</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art. “Salt” denotes acidic and/or basic salts formed with inorganic and/or organic acid and bases.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 6, ll. 40-59; col. 28, ll. 39-51; col. 29, l. 54 - col. 30, l. 1</p>	<p>CONSTRUCTION At least one compound falling within the scope of compounds that may result from formula III as further defined by the language of claim 1, or a salt thereof; where the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof.</p> <p>EVIDENCE ‘875 patent, col. 6, l. 44- col. 7, l. 43; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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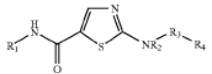
<p>‘875 claim 2</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, l. 52 - col. 29, l. 3</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘875 patent at col. 26, ll. 36-41; <i>id.</i> at col. 28, l. 52-col. 29, l. 3; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 22-col. 31, l. 11.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.</i>, col. 30, ll. 1-4</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder susceptible to treatment with the compound of formula IV, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘875 patent at col. 1, ll. 10-17; <i>id.</i> at col. 28, ll. 26-38.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase “‘in need of such treatment’ . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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	<p>“a compound of formula IV”</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 6, ll. 40-59; col. 28, ll. 39-51; col. 29, l. 54 - col. 30, l. 1; file histories of the ‘746 patent, 856 patent and ‘875 patent.</p>	<p>CONSTRUCTION The compound depicted by formula IV, generically known as dasatinib; or a salt thereof; wherein the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof. The claim term is exclusive of those compositions containing one or more compounds not claimed in claim 6, including, but not limited to, for example, impurities.</p> <p>EVIDENCE ‘875 patent at col. 6, ll. 44-54; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 42-col. 31, l. 3. ‘875 patent PH, Original Application; <i>id.</i>, 3/4/04 Preliminary Amendment; <i>id.</i>, 3/22/04 Office Action <i>See generally</i> file histories of the ‘746 patent, ‘856 patent and ‘875 patent. Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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<p>‘875 claim 3</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, l. 52 - col. 29, l. 3</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘875 patent at col. 26, ll. 36-41; <i>id.</i> at col. 28, l. 52-col. 29, l. 3; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 22-col. 31, l. 11.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.,</i> col. 30, ll. 1-4</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder susceptible to treatment with the compound of formula III, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘875 patent at col. 1, ll. 10-17; <i>id.</i> at col. 28, ll. 26-38.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment’ . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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	<p>“a compound of formula III”</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 6, ll. 40-59; col. 28, ll. 39-51; col. 29, l. 54 - col. 30, l. 1</p>	<p>CONSTRUCTION At least one compound falling within the scope of compounds that may result from formula III as further defined by the language of claim 1, or a salt thereof; where the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof.</p> <p>EVIDENCE ‘875 patent, col. 6, l. 44- col. 7, l. 43; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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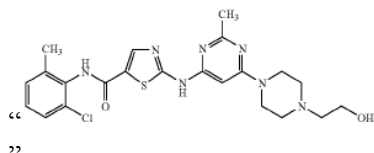
<p>‘875 claim 9</p>	<p>“wherein the cancer is resistant to treatment by STI-571”</p>	<p>CONSTRUCTION Wherein the cancer exhibits resistance to treatment by STI-571</p> <p>EVIDENCE <i>See, e.g.,</i> col. 28, ll. 26-38</p> <p><i>Merriam-Webster's Collegiate® Dictionary</i> 1564 (Deluxe ed. ©1998)</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, capable of determining if and who has determined that said cancer in patient is resistant to treatment by STI-571; wherein STI-571 is known as Gleevec™ (imatinib mesylate).</p> <p>EVIDENCE ‘875 patent at col. 28, ll. 35-38.</p> <p>‘875 patent PH, 8/26/05 Rejection at 2-3; <i>id.</i>, 12/23/05 Amendment at 11-12.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p> <p>Prescribing Information for Gleevec™, PHYSICIANS’ DESK REFERENCE 2357-60 (56th ed. 2002) (APO(Das)018678-81).</p>
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<p>‘875 claim 10</p>	<p>“wherein the cancer is resistant to treatment by STI-571”</p>	<p>CONSTRUCTION Wherein the cancer exhibits resistance to treatment by STI-571</p> <p>EVIDENCE <i>See, e.g.,</i> col. 28, ll. 26-38</p> <p><i>Merriam-Webster's Collegiate® Dictionary</i> 1564 (Deluxe ed. ©1998)</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, capable of determining if and who has determined that said cancer in patient is resistant to treatment by STI-571; wherein STI-571 is known as Gleevec™ (imatinib mesylate).</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>‘875 patent at col. 28, ll. 35-38.</p> <p>‘875 patent PH, 8/26/05 Rejection at 2-3; <i>id.</i>, 12/23/05 Amendment at 11-12.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p> <p>Prescribing Information for Gleevec™, PHYSICIANS’ DESK REFERENCE 2357-60 (56th ed. 2002) (APO(Das)018678-81).</p>
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<p>‘875 claim 11</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, l. 52 - col. 29, l. 3</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘875 patent at col. 26, ll. 36-41; <i>id.</i> at col. 28, l. 52-col. 29, l. 3; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 22-col. 31, l. 11.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.</i>, col. 30, ll. 1-4</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder susceptible to treatment with the compound of formula IV or a salt thereof, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘875 patent at col. 1, ll. 10-17; <i>id.</i> at col. 28, ll. 26-38.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment’ . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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“the compound of formula IV or a salt thereof”



CONSTRUCTION

Plain meaning as understood by a person of ordinary skill in the art. “Salt” denotes acidic and/or basic salts formed with inorganic and/or organic acid and bases.

Plain meaning as understood by a person of ordinary skill in the art.

EVIDENCE

See, e.g., col. 6, ll. 40-59; file histories of the ‘746 patent, 856 patent and ‘875 patent.

CONSTRUCTION

An amount of the compound depicted by formula IV, generically known as dasatinib; or a salt thereof; wherein the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof.

EVIDENCE

‘875 patent at col. 6, ll. 44-54; *id.* at col. 29, l. 54 – col. 30, l. 4; *id.* at col. 30, l. 42-col. 31, l. 3.

See also generally, file histories of the ‘746 patent, ‘856 patent and ‘875 patent.

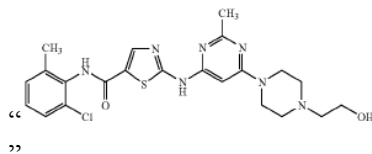
Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.

<p>‘875 claim 12</p>	<p>“wherein the chronic myelogenous leukemia (CML) is resistant to STI-571.”</p>	<p>CONSTRUCTION Wherein the chronic myelogenous leukemia (CML) exhibits resistance to treatment by STI-571</p> <p>EVIDENCE <i>See, e.g.,</i> col. 28, ll. 26-38, file history of the ‘875 patent</p> <p><i>Merriam-Webster's Collegiate® Dictionary</i> 1564 (Deluxe ed. ©1998)</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, capable of determining if and who has determined that said chronic myelogenous leukemia (CML) in the patient is resistant to treatment by STI-571; wherein STI- 571 is known as Gleevec™ (imatinib mesylate).</p> <p>EVIDENCE ‘875 patent at col. 28, ll. 35-38. ‘875 patent PH, 8/26/05 Rejection at 2-3; <i>id.</i>, 12/23/05 Amendment at 11-12.</p> <p><i>See also generally</i> file history of the ‘875 patent.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p> <p>Prescribing Information for Gleevec™, PHYSICIANS’ DESK REFERENCE 2357-60 (56th ed. 2002) (APO(Das)018678-81).</p>
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<p>‘875 claim 27</p>	<p>“administering to”</p>	<p>CONSTRUCTION To mete out or dispense or to give remedially</p> <p>EVIDENCE <i>Merriam-Webster's Collegiate® Dictionary</i> 15 (Tenth Edition, ©1993)</p> <p><i>See, e.g.,</i> col. 28, l. 52 - col. 29, l. 3</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, responsible for giving the therapeutic agent in question. Further, a therapeutic agent may be administered either alone or in combination with other therapeutic agents, where the claimed compounds are administered either prior to, simultaneously with, or following administration of the other therapeutic agents. Administration may occur in a single dose or in individual divided doses.</p> <p>EVIDENCE ‘875 patent at col. 26, ll. 36-41; <i>id.</i> at col. 28, l. 52-col. 29, l. 3; <i>id.</i> at col. 29, l. 54 – col. 30, l. 4; <i>id.</i> at col. 30, l. 22-col. 31, l. 11.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs” as implying a “measured and intended goal or condition.”).</p>
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	<p>“a subject in need thereof”</p>	<p>CONSTRUCTION An animal, including a human, in need thereof</p> <p>EVIDENCE <i>See, e.g.,</i> col. 30, ll. 1-4</p>	<p>CONSTRUCTION Any living organism having a protein-kinase associated disorder susceptible to treatment with the compound of formula IV or a salt thereof, as diagnosed by a second party, likely a physician or other clinician.</p> <p>EVIDENCE ‘875 patent at col. 1, ll. 10-17; <i>id.</i> at col. 28, ll. 26-38.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Jansen v. Rexall Sundown, Inc.</i>, 342 F.3d 1329, 1331-33 (Fed. Cir. 2003) (the phrase “<i>a method of treating or preventing macrocytic-megaloblastic anemia in humans . . . which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof</i>” required that the “need” for therapy be recognized and appreciated, and that the compound must be intentionally administered for treatment of the recited condition); <i>Schering Corp. v. Glenmark Pharm. Inc.</i>, No. 07-1334, 2008 WL 4307189, at *9 (D.N.J. Sept. 16, 2008) (Linares, J.) (phrase ““in need of such treatment” . . . has intent written into it” and requires an intent to use the drug for the purpose it was intended).</p>
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“the compound of formula IV or a salt thereof”



CONSTRUCTION

Plain meaning as understood by a person of ordinary skill in the art. “Salt” denotes acidic and/or basic salts formed with inorganic and/or organic acid and bases.

EVIDENCE

See, e.g., col. 6, ll. 40-59; col. 28, ll. 39-51; col. 29, l. 54 - col. 30, l. 1; file histories of the ‘746 patent, ‘856 patent and ‘875 patent

CONSTRUCTION

The compound depicted by formula IV, generically known as dasatinib or a salt thereof; wherein the term “salt” denotes acidic and/or basic salts formed with inorganic and/or organic acids and bases; including zwitterions (internal or inner salts) and quaternary ammonium salts; and further including both pharmaceutically-acceptable and other salts; prodrugs and solvates of the compound or salt thereof, and all stereoisomers of the compound or salt thereof. The claim term is also understood to include all polymorphs of the compound or salt thereof.

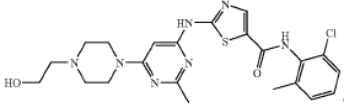
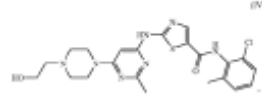
EVIDENCE

‘875 patent at 6, ll. 44-54; *id.* at col. 29, l. 54 – col. 30, l. 4; *id.* at col. 30, l. 42-col. 31, l. 3.

See also generally, file histories of the ‘746 patent, ‘856 patent and ‘875 patent.

Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.

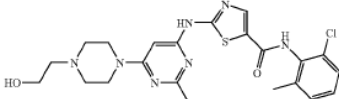
	<p>“wherein the cancer is resistant to STI-571”</p>	<p>CONSTRUCTION Wherein the cancer exhibits resistance to treatment by STI-571</p> <p>EVIDENCE <i>See, e.g.,</i> col. 28, ll. 26-38; file history of the ‘875 patent</p> <p><i>Merriam-Webster's Collegiate® Dictionary</i> 1564 (Deluxe ed. ©1998)</p>	<p>CONSTRUCTION The claim term requires two actors: one, the subject in need of treatment; two, another person, likely a physician, nurse practitioner or other clinician, capable of determining if and who has determined that said chronic myelogenous leukemia (CML) in the patient is resistant to treatment by STI-571; wherein STI- 571 is known as Gleevec™ (imatinib mesylate).</p> <p>EVIDENCE ‘875 patent at col. 28, ll. 35-38. ‘875 patent PH, 8/26/05 Rejection at 2-3; <i>id.</i>, 12/23/05 Amendment at 11-12.</p> <p><i>See also generally,</i> file history of the ‘875 patent.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p><i>See Eastman Kodak Co. v. Goodyear Tire & Rubber Co.</i>, 114 F.3d 1547, 1553 (Fed. Cir. 1997), <i>abrogated on other grounds by Cybor Corp. v. FAS Techs., Inc.</i>, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (construing “to” in the context of the claim and obeying “syntactic signs”</p> <p>Prescribing Information for Gleevec™, PHYSICIANS’ DESK REFERENCE 2357-60 (56th ed. 2002) (APO(Das)018678-81).</p>
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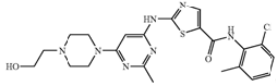
<p>'725 claim 1</p>	<p>“Crystalline monohydrate of the compound of formula (IV)”</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the monohydrate of the compound of formula IV in a crystalline form.</p> <p>EVIDENCE <i>American Heritage Dictionary of the English Language</i> 1137 (4th ed. ©2000)</p> <p><i>See, e.g.</i>, col. 43, l. 30 - col. 45, l. 32</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION Raw material produced by process conditions presented in the specification, with a particular arrangement of the following compound:</p>  <p>in three dimensional space that has a certain degree of long range order, with a 1:1 molar arrangement of water to compound formally associated in a unit crystal cell lattice.</p> <p>EVIDENCE '725 patent at claim 1; <i>id.</i> at col. 4, ll. 55- 67; <i>id.</i> at col. 24, l. 56 – col. 25, l. 43. '725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>PubChem Public Chemical Database, dasatinib – Compound Summary.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p>
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	<p>“which is characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1”</p>	<p>CONSTRUCTION</p> <p>Which is characterized by an x-ray powder diffraction pattern that is substantially identical to those shown in FIG. 1 taking into account variations due to measurement errors and dependent upon the measurement conditions employed, but not taking into account the exact order of intensity of the peaks. The ability to ascertain substantial identities of X-ray diffraction patterns is within the purview of one of ordinary skill in the art.</p> <p>EVIDENCE</p> <p><i>See, e.g.</i>, col. 41, l. 58 - col. 42, l. 13</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION</p> <p>The product being characterized must match the x-ray powder diffraction pattern presented in FIG. 1 of the patent specification, and further do so in such a way so as to uniquely identify the referenced “[c]rystalline monohydrate of the compound of formula (IV)</p> <div data-bbox="1325 354 1591 472" data-label="Chemical-Block"> </div> <p>EVIDENCE</p> <p>‘725 patent at claim 1; <i>id.</i> at col. 4, ll. 55-67; <i>id.</i> at col. 24, l. 56 – col. 25, l. 43; <i>id.</i> at col. 41, l. 57 – col. 42, l. 67.</p> <p>‘725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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<p>'725 claim 2</p>	<p>"The compound of claim 1"</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.</i>, claim 1; Fig. 2; col. 4, ll. 66-67</p>	<p>CONSTRUCTION The compound defined by claim 1, including all limitations of claim 1.</p> <p>EVIDENCE '725 patent at claim 1; <i>id.</i> at col. 4, ll. 55- 67; <i>id.</i> at col. 24, l. 56 – col. 25, l. 43.</p> <p>'725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>STEDMAN'S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL'S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p>
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	<p>“which is characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in FIG. 2.”</p>	<p>CONSTRUCTION Which is characterized by differential scanning calorimetry thermogram and thermogravimetric analysis patterns that are substantially identical to those shown in FIG. 2, having one peak at approximately 287° C and one broad peak between approximately 95° C and approximately 130° C. The ability to ascertain substantial identities of patterns is within the purview of one of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.,</i> col. 43, ll. 2-7; col. 45, ll. 15-22</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION The product being characterized must match both the differential scanning calorimetry thermogram and the thermogravimetric results presented in FIG. 2 of the patent specification, and further do so in such a way so as to uniquely identify the referenced “[c]rystalline monohydrate of the compound of formula (IV)</p> <div data-bbox="1325 407 1619 545" data-label="Chemical-Block"> </div> <p>At least the phrase “differential scanning calorimetry thermogram . . . in accordance with that shown in FIG. 2” is indefinite owing to the failure, in the patent specification to disclose the methodology for testing. (E.g., open pan, first run/second run).</p> <p>EVIDENCE ‘725 patent at claim 1; <i>id.</i> at col. 4, ll. 55- 66; <i>id.</i> at col. 24, 56 – col. 25, l. 43; <i>id.</i> at col. 43, ll. 1- 28. ‘725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>ANTHONY R. WEST, BASIC SOLID STATE CHEMISTRY 206-08 (2d ed. 1999) (APO(Das)026 017-19).</p>
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<p>'725 claim 3</p>	<p>“Crystalline monohydrate of the compound of formula (IV)”</p> 	<p>CONSTRUCTION</p> <p>Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the monohydrate of the compound of formula IV in a crystalline form.</p> <p>Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE</p> <p><i>American Heritage Dictionary of the English Language</i> 1137 (4th ed. ©2000)</p> <p><i>See, e.g.</i>, col. 43, l. 30 - col. 45, l. 32</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION</p> <p>Same as for claim 1.</p> <p>EVIDENCE</p> <p>'725 patent at claim 1; <i>id.</i> at col. 4, ll. 55- 66; <i>id.</i> at col. 24, l. 56 – col. 25, l. 43; <i>id.</i> at col. 41, l. 41 – col. 42, l. 67.</p> <p>'725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>PubChem Public Chemical Database, dasatinib – Compound Summary.</p> <p>STEDMAN'S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL'S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p>
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	<p>“which is characterized by an x-ray powder diffraction pattern (Cu k_{α} γ=1.5418 Å at a temperature of about 23° C.) comprising four or more 2θ values selected from the group consisting of: 18.0±0.2, 18.4±0.2, 19.2±0.2, 19.6±0.2, 21.2±0.2, 24.5±0.2, 25.9±0.2, and 28.0±0.2”</p>	<p>CONSTRUCTION Which is characterized by XRPD pattern taken with Cu k_{α} λ=1.5418 Å at a temperature of about 23° C, having at least four 2θ values selected from the group consisting of: 18.0±0.2, 18.4±0.2, 19.2±0.2, 19.6±0.2, 21.2±0.2, 24.5±0.2, 25.9±0.2, and 28.0±0.2.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 44, ll. 27-49</p> <p>Certificate of correction, filed May 11, 2010, deleting γ, inserting λ</p>	<p>CONSTRUCTION The product being characterized must uniquely identify the referenced “[c]rystalline monohydrate of the compound of formula (IV)</p> <p style="text-align: center;">(IV)</p>  <p>...”</p> <p>And generate an x-ray powder diffraction pattern using the methodology provided (CuKα γ=1.5418 Å at a temperature of about 23° C.).</p> <p>The term “2θ values” is vague and indefinite. “selected from the group consisting of” is Markush language, but in the context of the claims is vague and indefinite;</p> <p>To the extent variance is permitted, it is not supported by the claims; is indefinite and not supported by the written description; and violates the Markush concept.</p> <p>EVIDENCE ‘725 patent at claim 1; <i>id.</i> at col. 4, ll. 55- 66; <i>id.</i> at col. 24, l. 56 – col. 25, l. 43; <i>id.</i> at col. 41, l. 41 – col. 42, l. 67.</p> <p>‘725 patent FH, 9/18/07 Office Action at 2-7; <i>id.</i>, 12/18/07 Amendment at 1-7.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>SCINTAG, INC., CHAPTER 7: BASICS OF X-RAY DIFFRACTION 7.10 (1999) (APO(Das)026 039).</p>
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<p>'725 claim 4</p>	<p>“the compound of claim 3”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.</i>, claim 3; col. 44, ll. 49-60</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 3; this construction renders claim 4 invalid for improper dependency.</p> <p>To the extent the claim is construed as limited to a particular crystal form, the claim is not enabled and/or not infringed because the crystal form no longer exists if it is to engage in any therapeutic activity.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
<p>'725 claim 5</p>	<p>“The compound of claim 3”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See</i> claim 3</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 3; this construction renders claim 5 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4 STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

	<p>“characterized by unit cell parameters approximately equal to the following: Cell dimensions: a(Å)=13.8632(7); b(Å)=9.3307(3); c(Å)=38.390(2); Volume=4965.9(4) Å³ Space group Pbca Molecules/unit cell 8 Density (calculated) (g/cm³) 1.354.”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.,</i> col. 44, ll. 49-60</p>	<p>CONSTRUCTION This term is indefinite, as it is internally contradictory to and with the underlying independent claim and the other claim text, and “approximately equal to” is likewise vague and indefinite.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
<p>’725 claims 6, 7</p>	<p>“A process for preparing the compound of claim 3”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, a process for preparing the crystalline monohydrate of the compound of formula (IV). <i>See</i> claim 3.</p> <p>EVIDENCE <i>See</i> claim 3</p>	<p>CONSTRUCTION A process that must occur in the United States for preparing.</p> <p>The term is vague and indefinite in the context of the claim.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4; 35 U.S.C. § 271(a)</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

<p>'725 claim 8</p>	<p>“The compound of claim 3”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.</i>, claim 3; col. 15, ll. 28-56</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 3; this construction renders claim 8 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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	<p>“wherein the compound is substantially pure”</p>	<p>CONSTRUCTION The compound itself having a purity greater than 90 percent. The “substantially pure” compound may be employed in pharmaceutical compositions to which other desired components are added, for example, excipients, carriers, or active chemical entities of different molecular structure.</p> <p>EVIDENCE <i>See, e.g.,</i> col. 15, ll. 28-56</p>	<p>CONSTRUCTION The term is indefinite, particularly in the context of the claim language.</p> <p>Apotex recognizes that the specification states, “The present invention describes crystalline forms of the compound of formula (IV) in substantially pure form. As used herein, ‘substantially pure’ means a compound having a purity greater than 90 percent, including 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, and 100 percent.”</p> <p>However, a compound in and of itself cannot be “90 percent” or “99 percent” pure. A compound is what it is.</p> <p>A bulk drug substance, for example, may be a composition that contains 99% by measured weight of a particular compound; a different composition would be one that contains 99% molar amounts of a particular compound; a different composition would be one that contains 99% of a particular compound by volume. All would produce different results in the context of an infringement analysis.</p> <p>Further, a monohydrate crystal by definition cannot be at least 99% pure compound, because such material will necessarily contain water on a 1:1 molar ratio basis.</p> <p>EVIDENCE ‘725 patent at col. 15, ll. 27- 30.</p> <p>STEVEN’S ZUMDAHL, CHEMISTRY 21 (1986) (APO(Das)026 022-26).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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<p>'725 claim 9</p>	<p>“The compound of claim 3”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.</i>, claim 3; Fig. 2; col. 45, ll. 16-19</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 3; this construction renders claim 9 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4. STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11). CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029). Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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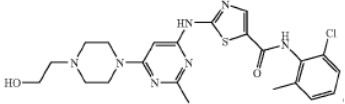
<p>“being further characterized by a differential scanning calorimetry having a broad peak between approximately 95° C and 13° C”</p>	<p>CONSTRUCTION Being further characterized by a differential scanning calorimetry having a broad peak between about 95° C and about 130° C. This peak can be variable but corresponds to the loss of one water of hydration on thermogravimetric analysis.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 45, ll. 16-19</p> <p>Certificate of correction, filed May 11, 2010, deleting 13°, inserting 130°</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION The product being characterized must match the stated results.</p> <p>The term “broad peak” is vague and indefinite. The term “peak” is not routinely used in the context of analyzing differential scanning calorimetry data. To the extent the term is intended to refer to endotherms or exotherms that can appear in a DSC trace, the claim language is indefinite and/or non-enabled.</p> <p>“Approximately” is indefinite in the context of the claims.</p> <p>At least the phrase “differential scanning calorimetry” is indefinite owing to the failure to disclose the methodology for testing. (E.g., open pan, first run/second run).</p> <p>EVIDENCE ‘725 patent at col. 45, ll. 16-19; <i>id.</i> at Fig. 2.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>ANTHONY R. WEST, BASIC SOLID STATE CHEMISTRY 206-08 (2d ed. 1999) (APO(Das)026 017-19).</p>
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	<p>“which corresponds to the loss of one water of hydration on thermogravimetric analysis”</p>	<p>CONSTRUCTION Which corresponds to a weight loss attributable to one water of hydration on thermogravimetric analysis</p> <p>EVIDENCE <i>See, e.g.,</i> col. 45, ll. 16-19</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION The claim language makes no sense in context, because a “compound” does not lose water.</p> <p>In general, if the claim were not internally contradictory, the language out of context would indicate that there is a peak in the DSC that must correspond and otherwise perfectly align to a TGA test result on the same sample being tested in which a precise, specific ratio of molecule(s) of water that constituted water formally associated in the unit cell of a crystal lattice is released (e.g., lost) in the specified test period.</p> <p>This claim language is vague and indefinite in the context of the remainder of the claim.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p>
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'725 claim 10	"The compound of claim 9"	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.,</i> claim 9; Fig. 2; col. 45, ll. 25-28</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 3, which in turn is identified in claim 9; this construction renders claim 10 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN'S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL'S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
	"which is further characterized by a weight loss of 3.48% by thermogravimetric analysis between 50° C and 175° C"	<p>CONSTRUCTION Which is further characterized by a weight loss of 3.48% by thermogravimetric analysis between 50° C and 175° C, taking into account variations due to measurement errors and dependent upon the measurement conditions employed.</p> <p>EVIDENCE <i>See, e.g.,</i> col. 45, ll. 25-28.</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION In isolation, the phrase would refer to material that is being subjected to the testing.</p> <p>In general, if the claim were not internally contradictory, the language out of context would indicate that there is an instrumental measured weight loss of the stated amount being sampled between the stated temperature range.</p> <p>However, this claim language is vague and indefinite in the context of the remainder of the claim. The "weight loss" claim language makes no sense in context, or is not enabled, because a "compound" does not lose weight.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

<p>'725 claim 11</p>	<p>“The compound of claim 9”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.</i>, claim 9; Fig. 2; col. 45, ll. 15-22</p>	<p>CONSTRUCTION See claim 10, above.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
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<p>“wherein the differential scanning calorimetry further has a peak at approximately 287° C”</p>		<p>CONSTRUCTION Characterized by differential scanning calorimetry with a peak located at about 287° C which corresponds to the melt of the dehydrated form of the compound of formula (IV)</p> <p>EVIDENCE <i>See, e.g.</i>, col. 45, ll. 20-22</p>	<p>CONSTRUCTION The product being characterized must match the stated results.</p> <p>The term “broad peak” is vague and indefinite. The term “peak” is not routinely used in the context of analyzing differential scanning calorimetry data. To the extent the term is intended to refer to endotherms or exotherms that can appear in a DSC trace, the claim language is indefinite and/or non-enabled.</p> <p>“Approximately” is indefinite in the context of the claims.</p> <p>At least the phrase “differential scanning calorimetry” is indefinite owing to the failure to disclose the methodology for testing. (E.g., open pan, first run/second run).</p> <p>EVIDENCE ‘725 patent at col. 45, ll. 20- 22; <i>id.</i> at Fig. 2.</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>ANTHONY R. WEST, BASIC SOLID STATE CHEMISTRY 206-08 (2d ed. 1999) (APO(Das)026 017-19).</p>
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<p>'725 claim 12</p>	<p>“Crystalline monohydrate of the compound of formula (IV)”</p> 	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, <i>i.e.</i>, the monohydrate of the compound of formula IV in a crystalline form.</p> <p>Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>American Heritage Dictionary of the English Language</i> 1137 (4th ed. ©2000)</p> <p><i>See, e.g.</i>, col. 43, l. 30 - col. 45, l. 32</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION Same as for claim 1, above.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p> <p>PubChem Public Chemical Database, dasatinib – Compound Summary.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p>
	<p>“which is characterized by a differential scanning calorimetry having a broad peak between approximately 95° C and 130° C”</p>	<p>CONSTRUCTION Which is characterized by a differential scanning calorimetry having a broad peak between about 95° C and about 130° C. This peak can be variable but corresponds to the loss of one water of hydration on thermogravimetric analysis.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 45, ll. 16-19</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION Same issues as set forth in claims 2, 9, above.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
	<p>“which corresponds to the loss of one water of hydration on thermogravitmetric analysis”</p>	<p>CONSTRUCTION Which corresponds to a weight loss attributable to one water of hydration on thermogravimetric analysis</p> <p>EVIDENCE <i>See, e.g.</i>, col. 45, ll. 16-19</p> <p>Dr. Atwood</p>	<p>CONSTRUCTION Same issues as set forth in claims 2, 9, 10 above.</p> <p>EVIDENCE Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

<p>'725 claim 13</p>	<p>“the compound of claim 12”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art, i.e., the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.,</i> claim 12; col. 15, ll. 49-52; col. 26, ll. 31-35</p>	<p>CONSTRUCTION Same issues as claim 4, above.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
<p>'725 claim 14</p>	<p>“the compound of claim 9”</p>	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.,</i> claim 9; col. 15, ll. 49-52; col. 26, ll. 31-35</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 9; this construction renders claim 14 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN’S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL’S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

'725 claim 15	"the compound of claim 12"	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art , <i>i.e.</i>, the crystalline monohydrate of the compound of formula (IV).</p> <p>EVIDENCE <i>See, e.g.</i>, claim 12; col. 15, ll. 28-56</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 12; this construction renders claim 15 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN'S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL'S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
	"wherein the compound is substantially pure"	<p>CONSTRUCTION The compound itself having a purity greater than 90 percent. The "substantially pure" compound may be employed in pharmaceutical compositions to which other desired components are added, for example, excipients, carriers, or active chemical entities of different molecular structure.</p> <p>EVIDENCE <i>See, e.g.</i>, col. 15, ll. 28-56</p>	<p>CONSTRUCTION See discussion in claim 8, above.</p> <p>EVIDENCE '725 patent at col. 15, ll. 27-30.</p> <p>STEVEN S. ZUMDAHL, CHEMISTRY 21 (1986) (APO(Das)026 022-26).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>

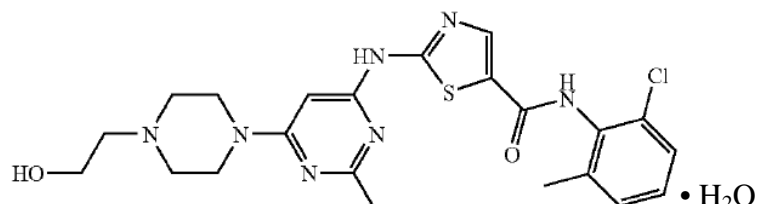
'725 claim 16	"the compound of claim 9"	<p>CONSTRUCTION Plain meaning as understood by a person of ordinary skill in the art.</p> <p>EVIDENCE <i>See, e.g.,</i> claim 9; col. 15, ll. 28-56</p>	<p>CONSTRUCTION The compound that is identified and defined as such in claim 9; this construction renders claim 16 invalid for improper dependency.</p> <p>EVIDENCE 35 U.S.C. § 112, ¶ 4.</p> <p>STEDMAN'S MEDICAL DICTIONARY 392-93, 838 (27th ed. 2000) (APO(Das)026 009-11).</p> <p>CHURCHILL'S ILLUSTRATED MEDICAL DICTIONARY 880 (1989) (APO(Das)026 029).</p> <p>Apotex expects to rely on expert testimony of one of skill in the art regarding the interpretation of this claim term.</p>
	"wherein the compound is substantially pure"	<p>CONSTRUCTION The compound itself having a purity greater than 90 percent. The "substantially pure" compound may be employed in pharmaceutical compositions to which other desired components are added, for example, excipients, carriers, or active chemical entities of different molecular structure.</p> <p>EVIDENCE <i>See, e.g.,</i> col. 15, ll. 28-56</p>	<p>CONSTRUCTION See discussion in claim 8, above.</p> <p>EVIDENCE '725 patent col. 15, ll. 27-30.</p> <p>STEVEN S. ZUMDAHL, CHEMISTRY 21 (1986) (APO(Das)026 022-26).</p> <p>Apotex expects to rely on expert testimony of one of skill the art regarding the interpretation of this claim term.</p>

EXHIBIT C

EXHIBIT C

Supplemental Summary of Proposed Testimony of Dr. Jerry Atwood

1. Claim 1 of the '725 patent recites a "[c]rystalline monohydrate of the compound of formula (IV)" "which is characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1." This means that the claimed crystalline monohydrate is characterized by an x-ray powder diffraction ("XRPD") pattern that is substantially identical to those shown in FIG. 1 taking into account variations due to measurement errors and dependent upon the measurement conditions employed, but not taking into account the exact order of intensity of the peaks. The specification of the '725 patent specifically states that "relative intensities may also vary depending upon experimental conditions and, accordingly, the exact order of intensity should not be taken into account" in determining whether the XRPD of the crystalline monohydrate is substantially in accordance with FIG. 1. (Col. 41, l. 58 - col. 42, l. 13). The ability to ascertain substantial identities of X-ray diffraction patterns is within the purview of one of ordinary skill in the art.
2. The plain meaning of a monohydrate of the compound of formula IV is represented by:



3. Claim 2 of the '725 patent recites a crystalline monohydrate of the compound of formula (IV) "which is characterized by a differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in FIG. 2." This means that the claimed crystalline monohydrate is characterized by differential scanning calorimetry and thermogravimetric analysis patterns that are substantially identical to those shown in FIG. 2, having one peak at approximately 287° C and one broad peak between approximately 95° C and approximately 130° C. The ability to ascertain substantial identities of patterns is within the purview of one of ordinary skill in the art.
4. Claim 9 of the '725 patent recites that the compound of claim 3, *i.e.*, the crystalline monohydrate of the compound of formula (IV), "being further characterized by a differential scanning calorimetry having a broad peak between approximately 95° C and 13° C which corresponds to the loss of one water of hydration on thermogravimetric analysis." This means that the compound is being further characterized by a differential scanning calorimetry having a broad peak between about 95° C and about 130° C. This

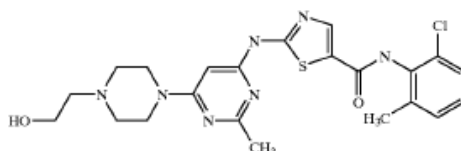
peak can be variable but corresponds to the loss of one water of hydration on thermogravimetric analysis. (Col. 45, ll. 16-19.) “13° C” is a typographic error and is meant to be “130° C.” This is clear from the specification and the certificate of correction filed with the USPTO on May 11, 2010.

5. The phrase “corresponds to the loss of one water of hydration on thermogravimetric analysis” means that the broad peak corresponds to a weight loss attributable to one water of hydration on thermogravimetric analysis.
6. Claim 10 of the ’725 patent recites that the compound of claim 9 “which is further characterized by a weight loss of 3.48% by thermogravimetric analysis between 50° C and 175° C.” This means that the compound is being further characterized by a weight loss of 3.48% by thermogravimetric analysis between 50° C and 175° C, taking into account variations due to measurement errors and dependent upon the measurement conditions employed.
7. Claim 12 of the ’725 patent recites a crystalline monohydrate of the compound of formula (IV) “which is characterized by a differential scanning calorimetry having a broad peak between approximately 95° C and 130° C which corresponds to the loss of one water of hydration on thermogravimetric analysis.” This means that the claimed crystalline monohydrate is characterized by a differential scanning calorimetry having a broad peak between about 95° C and about 130° C. This peak can be variable, but corresponds to the loss of one water of hydration on thermogravimetric analysis.

EXHIBIT D

EXHIBIT D**Summary of Proposed Testimony of Dr. William L. Jorgensen**

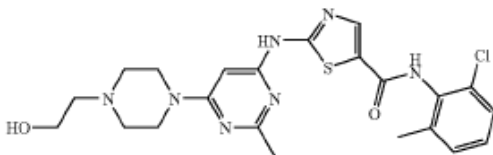
1. Claim 43 of the '746 patent and claim 1 of the '856 patent recite a compound with the following structure



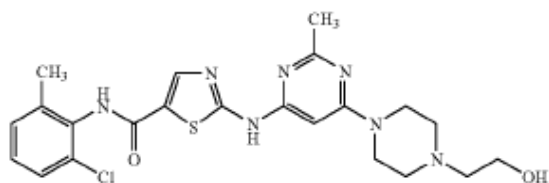
The '746 and the '836 patent identifies 'N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide as the name for this compound. (See the '746 patent, col. 213-214; the '856 patent, col. 219-220.)

2. This is evidenced by, *inter alia*, Example 455 in the '746, '856 and '875 patents, where the compound with the structure above is identified with the name, 'N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide.

3. The compound having the structure shown above is the same as the compound having the following structure



which can also be represented as



4. A person of ordinary skill would understand that the nitrogen of the amine connected to the 2-position of the thiazole and the nitrogen of the amide connected to 5-position of the thiazole are bonded to a hydrogen. It is an acceptable convention in the field of chemistry to omit the hydrogen of amines and amides when drawing the chemical structure. The specifications of the '746 and '856 patents consistently illustrate structures of chemical compounds without showing the hydrogen of amines or amides.

5. Claim 6 of the '746 patent contains a list of compounds, including 'N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide. For the reasons stated above, a person of ordinary skill in the art would understand that 'N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide represents the compound having the following equivalent chemical structures:

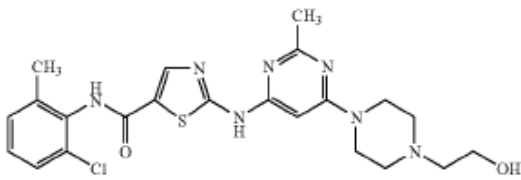
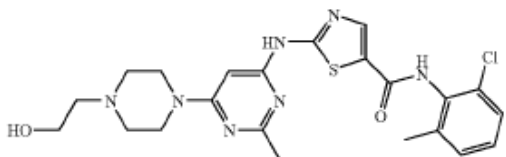
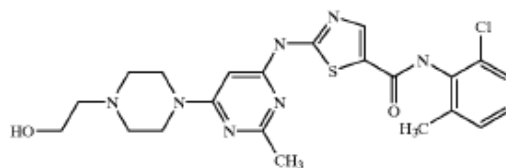
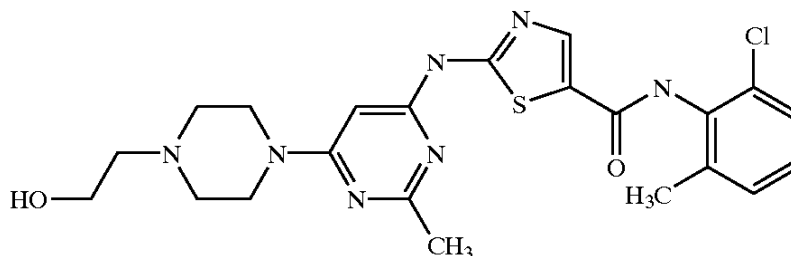


EXHIBIT E

Exhibit E: Summary of Proposed Testimony of Ariel Fernandez

1. Claim 43 of the '746 patent and claim 1 of the '856 patent claim the following compound:



This structure depicts the compound with all valences full with two exceptions: the nitrogen atom that bridges the thiazole and pyrimidine moieties, and the nitrogen of the amide that bridges the phenyl and thiazole moieties.

2. As all other valences are shown closed, including by a hydrogen atom (i.e., the hydroxyl moiety), one of ordinary skill in the art finds the structure open-ended. The general convention in organic chemistry is to show all hydrogen atoms or not; if some hydrogens are shown, it would be presumptuous to assume hydrogens are meant to fill open valences. Rather, one would assume that if hydrogens had been meant to fill the valences, the author would have indicated as such with atomic labels. Accordingly, one would find the above structure indefinite as to the complete chemical configuration.

3. Indeed, both the '746 patent and the '856 patent do not limit the positions in question to merely hydrogen. For example, the genus disclosed in the '746 patent includes not only hydrogen but alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, heterocyclo, or heterocycloalkyl as acceptable substituents for the nitrogen bridging the thiazole and pyrimidine moieties. ('746 patent at col. 2, ll. 5-48; col. 4, ll. 32-49, claims 1, 2, 3, 4, 5, 7; '856 patent at col. 2, ll. 5-col. 4, l. 57). Further, each of these

groups may be substituted, if desired, and may be connected to the nitrogen in question through another connecting atom or group. (*Id.*). Likewise, the amide shown connecting the thiazole and phenyl groups does not necessarily have to be substituted with hydrogen, and may in fact be substituted with hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, heterocyclo, heterocycloalkyl, possibly through a connecting atom or group; an amine, or together with the nitrogen atom to which they are attached complete a 3- to 8-membered saturated or unsaturated heterocyclic ring which is unsubstituted or substituted with additional moieties and which itself may be optionally fused to a substituted or unsubstituted benzene ring. ('746 patent col. 2, ll. 5-58; col. 4, ll. 32-39, claims 1, 2, 3, 4, 5, 7; '856 patent at col. 2, ll. 5-col. 4, l. 57).

4. Taking into account the lack of cohesion with regard to structural convention of the structure depicted in claim 43, and the large number of potential substituents from which to choose in both the '746 patent and the '856 patent, one of ordinary skill in the art would not be certain of the actual compound depicted by the figure in claim 43 of the '746 patent and claim 1 of the '856 patent.

EXHIBIT F

Exhibit F: Summary of Proposed Testimony of Gautam Desiraju

1. The '725 patent recites a "[c]rystalline monohydrate of the compound of formula (IV)" in at least claims 1, 3 and 12, which is incorporated within claims 2, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, and 16, which are dependent either directly or indirectly thereon. This means that the claimed solid-state form of the compound of formula (IV) is any crystal within a powder produced from a chemical synthetic procedure that yields the compound of formula (IV) in a regularly oriented arrangement in three dimensional space, and which has water formally associated in the lattice in a 1:1 stoichiometry.

2. At least claim 1 of the '725 patent also recites a crystalline monohydrate of the compound of formula (IV) "which is characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1." This means that the x-ray powder diffraction pattern must be such that the crystalline monohydrate form of the compound of formula (IV) must be able to be uniquely identified from other solid-state forms of the compound of formula (IV) and its hydrates by an ordinarily skilled artisan. The requirements to uniquely identify such a solid-state form will vary on a case by case basis and depend on knowledge of the samples at issue, as well as their particular characteristics, including, for example, sample purity, crystallinity of the sample, and the position and intensity of reflections observed in x-ray diffraction.

3. At least claims 2, 9, 11, and 12, as well as claims dependent either directly or indirectly thereon recite "differential scanning calorimetry." However, the technique of differential scanning calorimetry experiment is not described in sufficient detail because variations such as the instrument or sample configuration (*e.g.*, open or closed pans) or how many times the sample has been tested (*e.g.*, first or second run) can alter the nature of the transitions observed, the

positions at which transitions are observed, and the sharpness of said transitions, rendering the claim term indefinite.

4. At least claims 2, 9, 11, and 12, as well as claims dependent either directly or indirectly thereon include the limitation “peaks” in reference to differential scanning calorimetry. However, the term “peak” is not a term of art appropriate for use in reference to differential scanning calorimetry data given that the sample transitions observed by this technique have events, which correlate with changes in the sample.

5. At least claims 9 and 12, as well as claims dependent either directly or indirectly thereon include the limitation of a “broad peak” in reference to a characteristic occurring between “approximately” 95° C and 130° C¹ of a differential scanning calorimetry experiment. The term “broad peak” is indefinite as the breadth of a peak is not specified to an extent that it must clearly be interpreted as an instrumental response to a characteristic of the sample allegedly being claimed. Similarly, the term “approximately” is indefinite as the degree of acceptable variation in the sample allegedly claimed is not defined.

6. Claim 5 recites that the compound of claim 3 is “characterized by unit cell parameters approximately equal to the following:

Cell dimensions:

$$a(\text{\AA})=13.8632(7);$$

$$b(\text{\AA})=9.3307(3);$$

$$c(\text{\AA})=38.390(2);$$

$$\text{Volume}=4965.9(4) \text{\AA}^3$$

Space group Pbca

¹ Assuming for claim 3 that 13° C is indeed accepted to be 13[0]° C.

Molecules/unit cell 8

Density (calculated) (g/cm³) 1.354.”

The unit cell parameters are indefinite, at least because claim 3 is drawn to data obtained from powder x-ray diffraction, which does not under conventional circumstances allow the determination of the unit cell parameters of a crystalline form, particularly to the number of decimal places indicated in claim 5. Furthermore, the term “approximately equal to” is indefinite given that neither the claim nor the specification indicates what sort of variation may be expected.

7. At least claim 9 is directed to a compound characterized by exhibiting a feature “which corresponds to the loss of one water of hydration on thermogravimetric analysis.” This language does not make sense because a compound may not lose mass equivalent to one water and remain the same compound.

8. Claim 11 recites “The compound of claim 9, wherein the differential scanning calorimetry further has a peak at approximately 287° C.” Claim 11 depends on claim 9, which in turn depends on claim 3. Even if this claim were not internally contradictory, which it is, according to the data disclosed in the ‘725 patent, the “peak” at approximately 287° C is not affiliated with the sample present at lower temperatures, which, according to the data, undergoes a transition to a new form at about 180.50° C, and therefore the sample is no longer in the same form “at approximately 287° C” as the form having a broad “peak” at a temperature less than 180.50° C.